Window of Opportunity

Using FMEA's to Promote Safety

What is FMEA?

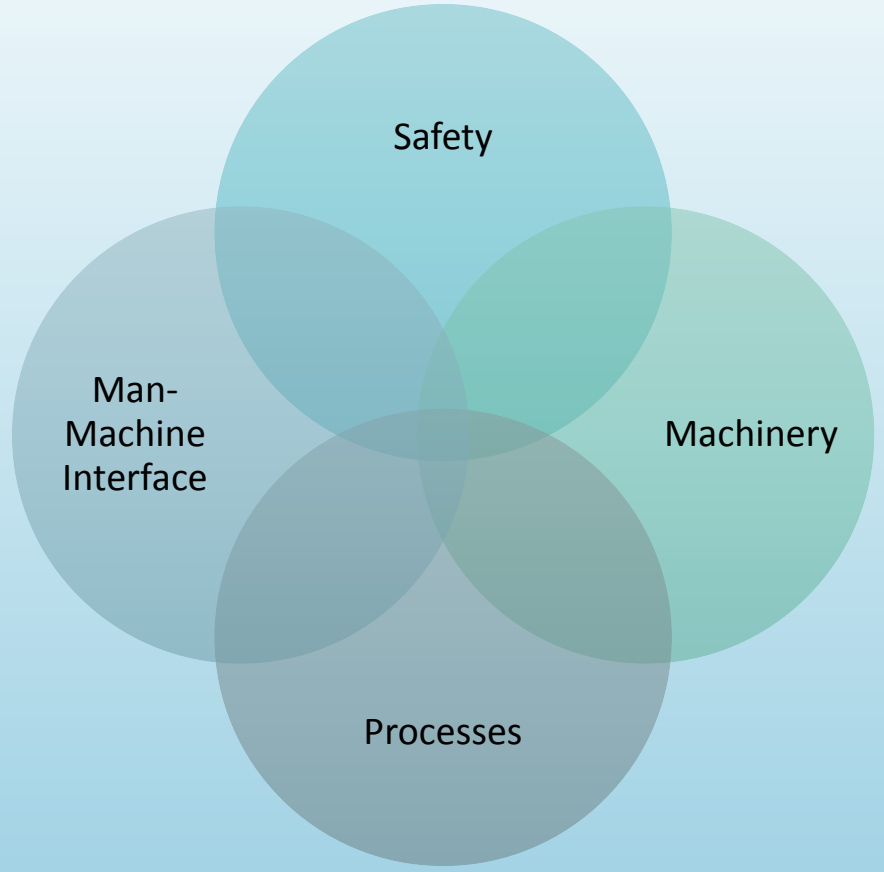
- Failure Mode and Effects Analysis
- Typically used in engineering design studies, it can be used over a broad range of functions
- Completed by a team of qualified individuals; not to be done by a select few
- Looks at a process, design, or system in a methodical way
- Can be used to design, to offer alternative solutions and identify improved risk, prior to installation, or after long periods of use
- Finds and corrects system weaknesses

A Method that is Designed to:

- Identify and understand potential failures in a system, what causes the failures, how the failures can affect the product, the operator, the process, the quality, and potential mitigation opportunities
- **Assesses risk** and prioritizes corrective actions
- **Minimizes performance degradation**

A Safety Perspective: One Step Further

- Identifies safety, processing, machine, and interfacing issues that can cause failures in the system
- Example:
  - A machine is functioning improperly, so an operator uses a different method to make it work right—without correcting the machine drift, and is subsequently injured.



- Greater understanding of how a system works, where it can fail and why, and how to mitigate.
- Provides for a method of knowledge retention when significant attrition occurs.
- Learning tool for ALL employees.
- Improves teaching platform for new employee training.
- “I’ve used this machine for 30 years and I never knew it could do THAT.” Improves current knowledge.
- Living document, so it changes when the process changes or when improvements are made. It is not static.
- Logs historical data.

- Plan to mitigate high risk process steps
- Developed into training programs such as TWI
- Written documents so that if information is lost, it is still available for future use.
- Teaches teamwork.
- Provides greater understanding of the process, machinery, bottlenecks, methods employees use, etc.
- Provides information for additional programs such as Preventive Maintenance, Predictive Maintenance, Critical Parts
- Job aids such as equipment check sheets, troubleshooting guides, and SOP’s

Benefits and Deliverables

FMEA Cons

- It takes a commitment from all team members
- Time consuming
- Documentation can become cumbersome

Next Steps

- Decide what the project is
  - Can be a machine, a process, software, design

- Define the Cross-Functional Team
  - Members must have knowledge or experience with the equipment, machinery, process, design, software

- Operators
- Maintenance
- Designer
- Engineer
- IT
- Safety
- Supervisors

- Schedule a permanent time to meet. Not showing up to a meeting is not acceptable.
- Expect that the project will take a minimum of 10 hours for a simple process, so plan accordingly
- Establish the rules of conduct. There will be brainstorming and much discussion in the process. The critical factor is agreement.
- Understand that Ranking ratings are subjective to a point. The team needs to clearly define what the ranking system will be that makes sense for the type of manufacturing or process. Eg: a batch process v. an assembly process will have differing measurement criteria.

FMEA SEVERITY (SEV) RATING

SEV	Severity	Product/Process/Safety Criteria
1	None	No Effect.
2	Very Minor	Defect would be noticed by most discriminating customers. A portion of the product may have to be reworked on line but in station.
3	Minor	Defect would be noticed by average customers. A portion of the product (<100%) may have to be reworked on line but out of station.
4	Very Low	Defect would be noticed by most customers. 100% of the product may have to be sorted and a portion (<100%) reworked.
5	Low	Comfort/convenience item(s) would be operable at a reduced level of performance. 100% of the product may have to be reworked.
6	Moderate	Comfort/convenience item(s) would be inoperable. A portion (<100%) of the product may have to be scrapped.
7	High	Product would be operable with reduced primary function. Product may have to be sorted and a portion (<100%) scrapped.
8	Very High	Product would experience complete loss of primary function. 100% of the product may have to be scrapped.
9	Hazardous w/Warning	Failure would endanger machine or operator with a warning.
10	Hazardous w/out Warning	Failure would endanger machine or operator (danger or death) without warning.

Ranking Systems- Severity

A	B	C	D	E
FMEA OCCURANCE (OCC) RATING				
OCC	**Severity**		**Product/Process Criteria**	**Safety Occurrence**
1	Remote		**1 in 1,500,00**	**Rarely Occurs**
2	Very Low		**1 in 150,000**	
3	Low		**1 in 15,000**	**Occurs 1 x in 10 years**
4	Low Moderate		**1 in 2,000**	
5	Moderate		**1 in 400**	**Occurs 1 x per year**
6	High Moderate		**1 in 80**	**Occurs more than 1 x per year**
7	High		**1 in 20**	**Occurs 1 x per month**
8	Very High		**1 in 8**	**Occurs > 1 x per month**
9	Hazard		**1 in 3**	**Occurs > 1 x per month**
10	High Hazard		**>1 in 2**	**Occurs daily**

Ranking System- Occurrence

FMEA DETECTION (DET) RATING		
DET	Severity	Criteria
1	Almost Certain	Current controls are almost certain to detect/prevent the failure mode.
2	Very High	Very High likelihood that current controls will detect/prevent the failure mode.
3	High	High likelihood that current controls will detect/prevent the failure mode.
4	Moderately High	Moderately High likelihood that current controls will detect/prevent the failure mode.
5	Moderate	Moderate likelihood that current controls will detect/prevent the failure mode.
6	Low	Low likelihood that current controls will detect/prevent the failure mode.
7	Very Low	Very Low likelihood that current controls will detect/prevent the failure mode.
8	Remote	Remote likelihood that current controls will detect/prevent the failure mode.
9	Very Remote	Very Remote likelihood that current controls will detect/prevent the failure mode.

Ranking System-Detection

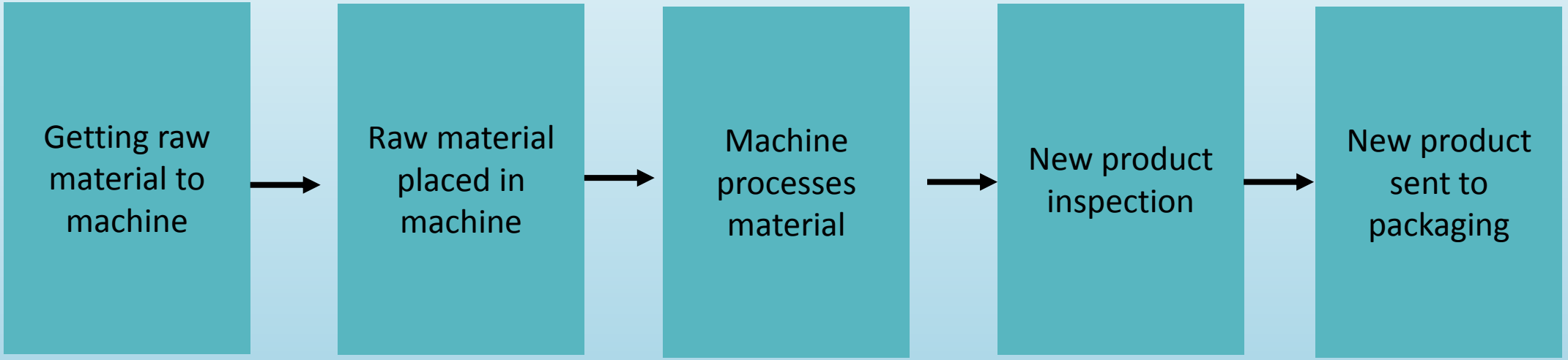
- Risk Priority Number is a numerical ranking of the defined risks.
- Calculating it is simple:

SEVERITY X OCCURRENCE X DETECTION = RPN

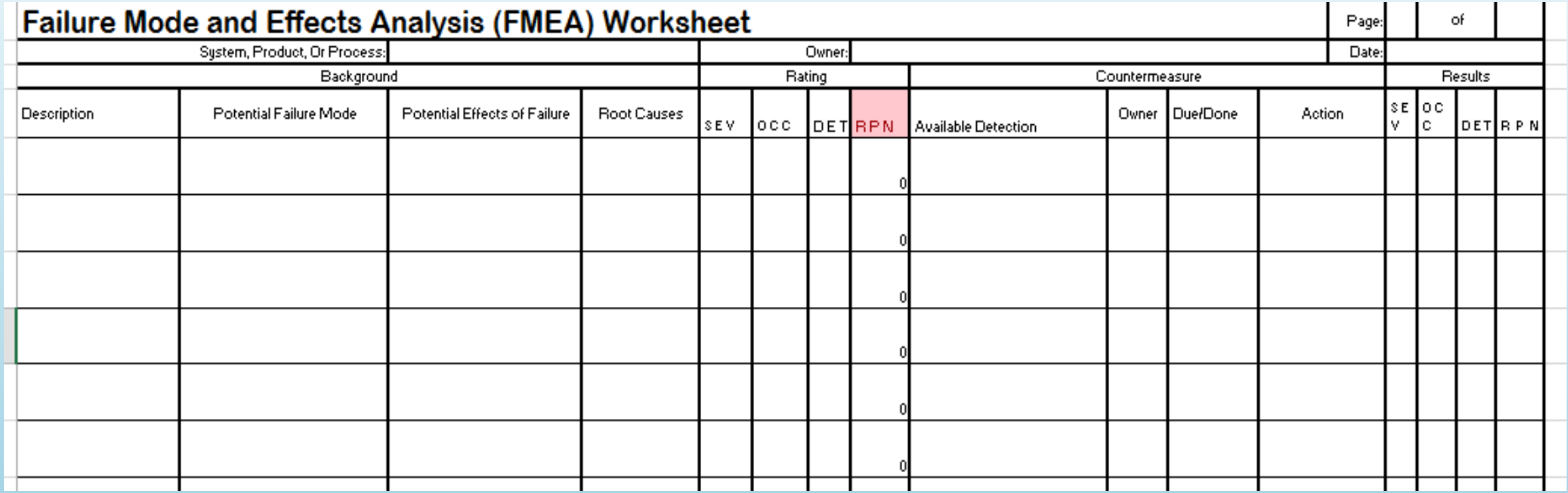
THE HIGHER THE NUMBER, THE GREATER THE RISK

Risk Priority Number

NODES



FLOW DIAGRAM



Failure Mode and Effects Analysis (FMEA) Worksheet

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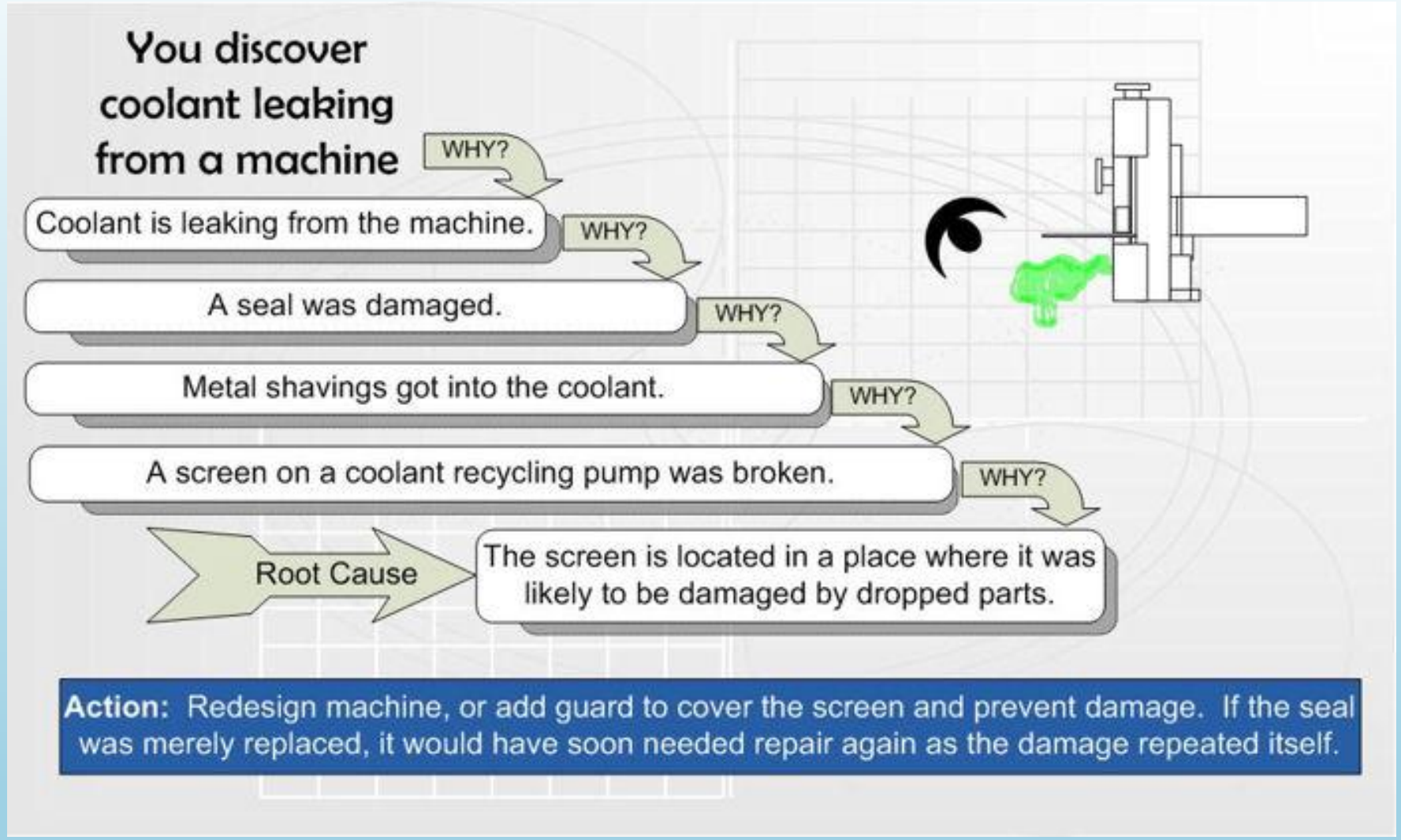
System, Product, Or Process:				Owner:								Date:						
Background				Rating				Countermeasure				Results						
Description	Potential Failure Mode	Potential Effects of Failure	Root Causes	SEV	OCC	DET	RPN	Available Detection	Owner	Due/Done	Action	SEV	OCC	DET	RPN			
							0											
							0											
							0											
							0											
							0											
							0											

FMEA MATRIX

POTENTIAL EFFECTS OF FAILURE

An EFFECT is the consequence on the system, the equipment, or the end user.

- Defining what the effects of the failure are
  - Injury
  - Hazard v. Harm
  - How it affects the system-software-process
  - How it affects the machine
  - How it affects the product
  - How it affects the environment
  - How it affects the method used (man-machine interface)


You discover coolant leaking from a machine
WHY?
Coolant is leaking from the machine.
WHY?
A seal was damaged.
WHY?
Metal shavings got into the coolant.
WHY?
A screen on a coolant recycling pump was broken.
WHY?
Root Cause
The screen is located in a place where it was likely to be damaged by dropped parts.
Action: Redesign machine, or add guard to cover the screen and prevent damage. If the seal was merely replaced, it would have soon needed repair again as the damage repeated itself.

Root Causes

- Apply Rankings for Severity, Occurrence and Detection using the scales defined by the team
- Team Effort-Everyone must ***agree*** on the ranking number for each root cause

Apply Rankings

- Dependent on the ranking scales
- Use a number that will be consistent across the company

Eg. RPN’s run from 0 to 900 based on the scale chosen

Your management agrees to look at/fix corrective actions for RPN’s over 600 on a priority basis (initially)

Set a Limit/Range of Priorities

- Brianstorming is an important part of the process
  - Creative, play “WHAT IF”
  - Provides a variety of options that can be explored from a feasibility and cost standpoint
  - Can be tested to determine effectiveness of the solution before it goes for feasibility/cost studies

Brainstorm Corrective Actions

- **How it affects the method used (man-machine interface)**

Normal v. expected v. what changed (why)

- Do procedures match what the operator needs to do?

- Are the exceptions identified and listed? What does the operator do when exceptions occur?

ASK THE RIGHT QUESTIONS

Don’t shortcut this step

LOOK BETWEEN

CONTACT INFORMATION:

Karen Robertson
km.robertson23214@gmail.com